UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/214,836	10/04/1999	CARL GUSTAV FIGDOR	2578-4230US	8137

7590 11/04/2003

Allen C Turner
TraskBritt
PO Box 2550
Salt Lake City, UT 84110

EXAMINER	
RAWLINGS, STEPHEN L	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/214,836	FIGDOR ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,4,11,14,15,19-22,24 and 25* is/are pending in the application.

4a) Of the above claim(s) *20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,4,11,14,15,19,21,22,24 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *2,4,11,14,15,19-22,24 and 25* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 31, 2003 in Paper No. 20 has been entered.

2. The amendment filed March 31, 2003 in Paper No. 19 is acknowledged and has been entered. Claims 2, 4, 11, 21, and 22 have been amended.

3. Claims 2, 4, 11, 14, 15, 19-22, 24, and 25 are pending in the application. Claim 20 has been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim.

4. Claims 2, 4, 11, 14, 15, 19, 21, 22, 24, and 25 are currently under prosecution.

Priority

5. In the previous Office Action mailed May 7, 2002 (Paper No. 15), Applicants were again advised that to obtain the benefits of the foreign filing date under 35 U.S.C. 119(a)-(d), Applicants should also file a claim for such priority as required by 35 U.S.C. 119(b). Applicants submitted an unsigned copy of a declaration, which claims the benefit of the filing date of EP 96201945.1. Accordingly, Applicants intent to meet the requirements 35 U.S.C. § 119(a)-(d) is acknowledged; however, the new declaration remains unexecuted and in this Office action, Applicants have not been afforded the claimed benefit of the earlier filing date of EP 96201945.1.

Grounds of Objection and Rejection Withdrawn

6. Unless specifically reiterated below, the grounds of objection and rejection set forth in the previous Office action mailed May 7, 2002 (Paper No. 15) have been withdrawn.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 21 and 24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons stated in section 11 of the previous Office Action mailed May 7, 2002 (Paper No. 15).

Applicants have traversed these grounds of rejection under 35 USC § 112, first paragraph arguing that the specification adequately enables one of skill in the art to make and use the vaccine as claimed. In addition, Applicants have argued that the peptide of which the claimed vaccine is composed, i.e., the peptide of SEQ ID NO: 1, binds to the HLA molecule at the surface of lymphocytes at an increased binding affinity compared to the peptide of SEQ ID NO: 9, which has alanine, rather than glutamine, at position 8 of the peptide's amino acid sequence.

Applicants' arguments have been carefully considered but not found persuasive. The claims are drawn to a vaccine, which, in this instance, are broadly interpreted as a claim to a means to prevent or treat melanoma. For the reasons set forth in the previous Office action mailed May 7, 2002 (Paper No. 15), the skilled artisan would not have a reasonable expectation of successfully using a vaccine to prevent the incidence or recurrence of melanoma without having need to first perform an undue amount of experimentation. The factors that have been considered in determining whether undue

experimentation would be required to use the claimed invention are summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986). These factors include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The fact that the peptide of SEQ ID NO: 1 has a greater binding affinity for the HLA molecule to which it binds than the peptide of SEQ ID NO: 9 does not obviate this ground of rejection, as the preponderance of factual evidence of record indicates that the claimed invention could not be used by the skilled artisan with a reasonable expectation of success without need of performing an undue amount of experimentation.

Note: Amending claims 21 and 24 to recite, for example, an immunogenic composition comprising the peptide of claim 4, rather than "a vaccine comprising the peptide of claim 4", can obviate this rejection.

9. Claims 2, 4, 14, 15, 19, 21, 22, 24 and 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reason set forth in section 18 of the Office action mailed May 7, 2002 (Paper No. 15).

Claims 2, 4, 11, 21, and 22 recite the limitation "wherein said peptide is able to induce an increased binding affinity towards lymphocytes". As stated in the previous Office action, there does not appear to be adequate antecedent basis in the specification to support the recitation of this limitation in the claims.

Applicants have traversed this ground of rejection arguing that the specification, as originally filed, provides proper and sufficient antecedence for the recitation of the

limitation in claims 2, 4, 11, 21, and 22. Applicants have pointed in particular to the disclosure of Example 3 at page 25.

Applicants' arguments have been carefully considered but not found persuasive. The disclosure at page 25 to which Applicants have referred in their arguments appears to support the recitation of a limitation, such as "wherein said peptide has an increased binding affinity for HLA-A*0201", but does not appear to support the recitation of the limitation "wherein said peptide is able to induce an increased binding affinity towards lymphocytes".

Note: Amending claims 2, 4, 11, 21, and 22 to recite, for example, "wherein said peptide has an increased binding affinity for HLA-A*0201", instead of "wherein said peptide is able to induce an increased binding affinity towards lymphocytes" can obviate this ground of rejection.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 2, 4, 11, 14, 15, 19, 21, 22, 24, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reason set forth in section 20 of the Office action mailed May 7, 2002 (Paper No. 15).

Claims 2, 4, 11, 14, 15, 19, 21, 22, 24, and 25 are vague and indefinite because claims 2, 4, 11, 21, and 22 recite the limitation "wherein said peptide is capable of inducing an increased binding affinity towards lymphocytes". Recitation of the limitation renders the claims vague and indefinite because the specification does not teach that the peptide can "induce" an increased binding affinity, but moreover it cannot be determined to what subject matter the claims require the peptide to induce to have a greater binding affinity towards lymphocytes. How is the peptide required to induce an increase in the binding affinity of this undisclosed subject matter?

Applicants have traversed this ground of rejection arguing that proper and sufficient antecedence in the specification, as originally filed, can be found in Example 3 at page 25.

Applicants' arguments have been carefully considered but not found persuasive. The Examiner disagrees with Applicants' assertion that proper and sufficient antecedence in the specification, as originally filed, can be found in Example 3 at page 25.

Note: Amending claims 2, 4, 11, 21, and 22 to recite, for example, the limitation, "wherein said peptide *has* an increased binding affinity towards *HLA-A*0201, or HLA-A*0201-expressing or –restricted* (if properly supported) *lymphocytes* compared to said peptide comprising a threonine at position 2" (italics added for emphasis) might obviate this ground of rejection.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 2, 11, 22, and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 5,844,075-A ('075) for the reason set forth in section 20 of the Office action mailed May 7, 2002 (Paper No. 15).

Applicants have traverses this ground of rejection under 35 USC § 102(b) arguing that the prior art did not test the claimed peptide, i.e., a peptide comprising SEQ ID NO: 2, to determine whether its binding affinity to HLA-A2.1 and its recognition by

reactive T-cells is increased or decreased in comparison to the peptide of SEQ ID NO: 46, the amino acid sequence of which, in the present application, has been assigned SEQ ID NO: 9.

Applicants' arguments have been carefully considered but have not been found persuasive. As set forth in the previous Office action, the prior art discloses the subject matter of claim 2, which is a peptide comprising the amino acid sequence set forth as SEQ ID NO: 2. SEQ ID NO: 2 is the amino acid sequence of SEQ ID NO: 9 but for the replacement of threonine at position 2 by valine. The prior art teaches a peptide comprising SEQ ID NO: 9 and teaches that the second amino acid of this peptide, which is a threonine, can be replaced by valine. See, in particular, claims 3, 8, and 10, in addition to the disclosures to which reference has already been made in the previous Office action. Furthermore, because the peptide of the prior art is the same as the peptide of claim 2, the peptide of the prior art is deemed to have the same properties as the peptide of claim 2, including, for example, the inherent property of having an increased binding affinity for the HLA molecules to which it binds at the surface of lymphocytes, as compared to the peptide of SEQ ID NO: 9.

14. Claims 4, 21, and 24 are rejected under 35 U.S.C. 102(a) as being anticipated by Bakker et al. (*International Journal of Cancer* **70**: 302-309, 1997).

Bakker et al. teaches a peptide comprising the amino acid sequence of SEQ ID NO: 1 and a composition comprising said peptide, which further comprises a pharmaceutically acceptable carrier or diluent.

Although claim 21 recites that the peptide of claim 2 is to be formulated as a vaccine, this recitation is not given weight in determining the novelty of the claimed invention, or in comparing the product of the prior art and the claimed product. The recitation is merely deemed a recitation of intended use, which does not serve to materially or structurally limit the claimed subject matter, or the peptide.

Note: Applicants can obviate this ground of rejection by filing a claim for benefit of the earlier filing date of EP 96201945.1, as required by 35 U.S.C. 119(b), and providing a certified copy of said priority document, provided that the claimed invention

is adequately disclosed by the document to meet the requirements of 35 USC §112, first paragraph.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claim 2, 11, 14, 19, 22, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,844,075-A ('075) for the reason set forth in section 20 of the Office action mailed May 7, 2002 (Paper No. 15).

Applicants have traversed the grounds of the rejection of the claims under 35 USC § 103(a), arguing that the prior art does not teach the claimed peptide for the reasons set forth in traversing the rejection of claims 2, 11, 22, and 25 under 35 USC § 102(e).

Applicants' arguments have been carefully considered but have not been found persuasive for the reasons set forth above in reply to Applicants' arguments traversing the rejection of claims 2, 11, 22, and 25 under 35 USC § 102(e).

Conclusion

17. No claims are allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax

phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
October 29, 2003

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600